REMARKS

In the Office Action dated September 15, 2003, the Examiner has set forth a requirement for restriction under 35 U.S.C. §121, alleging that the subject matter defined by the claims of the present application represents the following four separate and distinct inventions:

Group I. Claims 1-7 and 29-39, drawn to an enriched preparation of human embryonic stem cells, an undifferentiated human embryonic stem cell and methods of preparing undifferentiated human embryonic stem cells, classified in class 425, subclass 366 and 377.

Group II. Claims 8-28 and 40-59 drawn to a differentiated committed human progenitor cell line, a neural progenitor cell, an enriched preparation of neural progenitor cells, methods of inducing somatic differentiation of stem cells and differentiated progenitor cells, neurons, astrocytes and oligondendrocytes classified in class 435, subclass 377.

Group III. Claims 60-64, drawn to a method of producing an enriched preparation of human ES cell derived neural progenitor cells, classified in class 435, subclass 377.

Group IV. Claims 65-73, drawn to a method of transplanting ES derived neural progenitor cells in a host, a method of producing a stable graft and a method of modifying a nervous system of a host, classified in class 424, subclass 93.2.

The Examiner alleges that Groups I-IV are distinct, each from the other, because the methods of Groups I-IV are mutually exclusive and independent. Specifically, the Examiner alleges that the methods for preparing undifferentiated human embryonic stem cells (Group I), the methods for inducing somatic differentiation of stem cells (Group II), the methods of producing an enriched preparation of human ES cell derived neural progenitor cells (Group III), and the methods of transplanting neural progenitor cells in a host (Group IV), each require reagents materially different from the others. The implementation of the methods of any one group does not require the methods of any other group.

The Examiner states that because Groups I-IV are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

In order to be fully responsive to the Examiner's requirement for restriction, Applicants provisionally elect to prosecute the subject matter of Group IV, Claims 65-73, drawn to methods of transplanting ES derived neural progenitor cells in a host, a method of producing a stable graft and a method of modifying a nervous system of a host, classified in class 424, subclass 93.2, for continued prosecution. Applicants reserve the right to file one or more divisional applications directed to the non-elected subject matter in this application.

However, pursuant to 37 C.F.R. §§ 1.111 and 1.143, Applicants hereby traverse the Examiner's requirement for restriction and request reconsideration thereof in view of the following remarks.

An Examiner's authority to require restriction is defined and limited by statute:

> If two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions.

35 U.S.C. § 121, first sentence (emphasis added). The implementing regulations of the Patent and Trademark Office include the mandate that restriction is appropriate only in cases presenting inventions which are both independent and distinct, 37 C.F.R. §§1.141-142. Without a showing of independence and distinctness, a restriction requirement is unauthorized. In the present application, the claims which the Examiner has grouped separately are not "independent and distinct" so as to justify the restriction requirement.

Specifically, Applicants submit that Group I is directed to an undifferentiated human embryonic stem cell and an enriched preparation of human undifferentiated embryonic stem

cells, and methods of preparing these cells. These undifferentiated human embryonic stem cells are capable of differentiation into neural progenitor cells, and are the starting materials used in the methods of Group II and Group III. Therefore, Group I and Groups II-III are related and interdependent.

Furthermore, Groups II and III are also related and interdependent. Group II is directed to methods of inducing somatic differentiation of undifferentiated human stem cells, as well as to differentiated progenitor cells, neurons, astrocytes and oligondendrocytes. Group III is drawn to methods of producing an enriched preparation of neural progenitor cells derived from undifferentiated human ES cell. It is observed that the methods of Group II and Group III share the common start material (undifferentiated human stem cells) and at least one method step of inducing somatic differentiation of undifferentiated human stem cells. Therefore, Groups II and III are clearly interrelated and not independent.

Moreover, Applicants observe that Groups II-III are classified in the same class and subclass. The Examiner's attention is directed to MPEP § 808.02, which states "where however, the classification is the same and the field of search is the same and there is no clear indication of separate future classification and field of search, no reasons exist for dividing among related inventions". Because the classification of Group II and III are the same and because the Examiner has not provided any evidence of separate future classifications for this field of search, the restriction requirement at least with respect to Groups II and III is inconsistent with MPEP § 808.02.

Applicants further respectfully submit that Group IV is also related to Groups I-III. In particular, Group IV is directed to methods of transplanting neural progenitor cells in a host, methods of producing a stable graft and methods of modifying a nervous system of a host, all of

which employ the neural progenitor cells of Group II or the neural progenitor cells produced by the methods of Groups II or III.

Therefore, Groups I-IV are clearly related to each other as different aspects of a single invention. Notably, the courts have recognized that it is in the public interest to permit applicants to claim several aspects of their invention together in one application, as the applicants have done herein. The CCPA has observed:

> We believe the constitutional purpose of the patent system is promoted by encouraging applicants to claim, and therefore to describe in the manner required by 35 U.S.C. §112 all aspects as to what they regard as their invention, regardless of the number of statutory classes involved.

In re Kuehl, 456 F.2d 658, 666, 117 U.S.P.Q. 250, 256 (CCPA 1973). This interest is consistent with the practical reality that a sufficiently detailed disclosure supporting claims to one aspect of an invention customarily is sufficient to support claims in the same application to other aspects of the invention.

Applicants respectfully suggest that in view of the continued increase of official fees and the potential limitation of an applicant's financial resources, a practice which arbitrarily imposes restriction requirements may become prohibitive and thereby contravene the constitutional purpose to promote and encourage the progress of science and the useful arts. Moreover, under the regulatory changes as a consequence of the General Agreement on Trade and Tariffs (GATT), applicants are required to conduct simultaneous prosecution, as here, requiring excessive filing costs, or to otherwise compromise the term of related patent assets.

It is vital to all applicants that restriction requirements issue only with the proper statutory authorization, because patents issuing on divisional applications which are filed to prosecute claims that the Examiner held to be independent and distinct can be vulnerable to legal

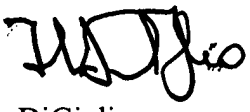
challenges alleging double patenting. The third sentence of 35 U.S.C. §121, which states that a patent issuing on a parent application "shall not be used as a reference" against a divisional application or a patent issued thereon, does not provide comfort to applicants against such allegations. The Court of Appeals for the Federal Circuit has declined to hold that § 121 protects a patentee from an allegation of same-invention double patenting, Studiengesellschaft Kohle GmbH v. Northern Petrochemical Co., 784 F.2d 351, 355, 288 U.S.P.Q. 837, 840 (Fed. Cir. 1986). In Gerber Garment Technology Inc. v. Lectra Systems Inc., 916 F.2d 683, 16 U.S.P.Q. 2d 1436 (Fed. Cir. 1990), the court held that §121 does not insulate a patentee from an allegation of "obviousness-type" double patenting, and in fact affirmed the invalidation on double patenting grounds of a patent that had issued from a divisional application filed following a restriction requirement. Furthermore, it is far from clear that the step of filing a terminal disclaimer is available to resolve a double patenting issue that arises after the issuance of a patent on the divisional application.

All these considerations indicate that the imposition of a restriction requirement with inadequate authority can lead to situations in which an applicant's legitimate patent rights are exposed to uncertainty and even extinguished. Accordingly, to protect a patentee's rights and to serve the public interest in the legitimacy of issued patents, Applicants respectfully urge the Examiner not to require restriction in cases such as the present application wherein various aspects in a unitary invention are claimed.

Finally, Applicants respectfully submit that a determination to make the pending restriction requirement final must evidence the patentable distinctness of all four defined groups, one from the other, as presented by the Examiner.

In view of the foregoing comments, it is respectfully urged that the Examiner reconsider and withdraw the requirement for restriction and provide an action on the merits with respect to all the claims.

Respectfully submitted,



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